K121320
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510(k) Summary

AUG 10 2012

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Date Prepared: June 29, 2012

Proprietary Name: Medyssey C7 Anterior Cervical Interbody Fusion Cage

Classification Name: 87 ODP– Orthosis, intervertebral body fusion device, cervical 21 CFR 888.3080, Class II

Predicate Device:
- SpineCraft, LLC ORIO Intervertebral Body Fusion Cages (K090887)
- Custom Spine, Inc. Pathway ACIF (K092904)
- Biomet Spine C-Thru Anterior Spinal System (K092336)

Product Description: The Medyssey C7 Anterior Cervical Interbody Fusion Cage system consists of a series of PEEK (polyetheretherketone) cervical interbody spacers of various footprints and thicknesses. The C7 ACIF cages have ridges on their superior and inferior surfaces to prevent migration, and graft windows to allow for bony fusion. Tantalum markers are incorporated into the devices to allow for radiographic visualization of the implants.

Indications for Use:
The C7 Anterior Cervical Intervertebral Fusion Cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level (C2-T1). DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. C7 Anterior Cervical Intervertebral Fusion Cages are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach and packed with autogenous bone. C7 Anterior Cervical Intervertebral Fusion Cages are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Summary of Technological Characteristics:
The Medyssey C7 Anterior Cervical Interbody Fusion Cage System consists of a series of PEEK (polyetheretherketone) Optima LT1 (from Invibio) interbody spacers with tantalum radiographic markers. The C7 ACIF devices are trapezoidal in shape, have a central graft containment cavity, have ridges to resist expulsion and have an anterior threaded hole for instrument attachment. The predicate ORIO ACIF and Pathway ACIF devices are also made from PEEK, with tantalum markers, are trapezoidal in shape, have a central graft containment cavity, ridges to resist expulsion and an anterior threaded hole for instrument attachment.

Medyssey has determined that the minor differences between proposed device and the predicate devices will not impact the safety or effectiveness of the anterior cervical interbody fusion system for its intended use. Analysis has shown that the proposed device is equivalent to the predicate devices.

Identification of Legally Marketed Predicate Device:
Documentation was provided, which demonstrates that the subject Medyssey C7 Anterior Cervical Cage is substantially equivalent to the predicate devices the SpineCraft, LLC ORIO Intervertebral Body Fusion Cages (K090887), Custom Spine, Inc. Pathway ACIF (K092904) and Biomet Spine C-Thru Anterior Spinal System (K092336). The proposed Medyssey device has the same indications for use and is manufactured from the same material. The minor differences in the design were evaluated through testing and do not affect the safety and efficacy of the device for its intended use.

Brief Discussion of Non-Clinical Tests Submitted:
Numerous tests were performed on the Medyssey Anterior Cervical Interbody Fusion System. The tests performed are recommended by the FDA guidance document for intervertebral body fusion devices, including ASTM F2077 and ASTM F2267. List of Tests is below:

- Static Compression
- Static Torsion
- Static Compressive Shear
- Dynamic Compression
- Subsidence
- Expulsion

Conclusions from Non-Clinical Tests:
Based on the testing and comparison analysis to the predicate devices provided in this premarket notification submission, Medyssey believes that the subject Medyssey C7 Anterior Cervical Cage System is substantially equivalent to the SpineCraft, LLC ORIO Intervertebral Body Fusion Cages (K090887), Custom Spine, Inc. Pathway ACIF (K092904) and Biomet Spine C-Thru Anterior Spinal System (K092336)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 10 2012

Medyssey Company Limited
% Mr. Michael Kvitnitsky
Chief Operating Officer
8001 North Lincoln Avenue, Suite 401
Skokie, Illinois 60077

Re: K121320
Trade/Device Name: Medyssey C7 Anterior Cervical Interbody Fusion Cages
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: ODP
Dated: June 30, 2012
Received: July 23, 2012

Dear Mr. Kvitnitsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K121320

Device Name: Medyssey C7 Anterior Cervical Interbody Fusion Cages

Indications for Use:

The C7 Anterior Cervical Intervertebral Fusion Cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level (C2-T1). DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. C7 Anterior Cervical Intervertebral Fusion Cages are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach and packed with autogenous bone. C7 Anterior Cervical Intervertebral Fusion Cages are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use_____ (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121320